PTO 08-6902

CC=JP
DATE=19841031
KIND=A
PN=59192366

PROSTHETIC HEART VALVE
[JINKO SHINZO BEN]

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UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. AUGUST 2008
TRANSLATED BY SCHREIBER TRANSLATIONS, INC.

PUBLICATION COUNTRY	(10):	JP
DOCUMENT NUMBER	(11):	59192366
DOCUMENT KIND	(12):	A
PUBLICATION DATE	(43):	18941031
APPLICATION NUMBER	(21):	58-67389
APPLICATION DATE	(22):	19830415
INTERNATIONAL CLASSIFICATION	(51):	A61F 1/22//B32B 19/04
PRIORITY COUNTRY	(33):	N/A
PRIORITY NUMBER	(31):	N/A
PRIORITY DATE	(32):	N/A
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DESIGNATED CONTRACTING STATES	(81):	N/A
TITLE	(54):	PROSTHETIC HEART VALVE
FOREIGN TITLE	[54A]:	JINKO SHINZO BEN

2. Claims

(1) A prosthetic heart valve, which is made by coating a polymer material with amorphous carbon or diamond.

(2) The prosthetic heart valve according to claim 1, wherein said polymer material is polyurethane or Teflon.

3. Detailed Description of the Invention

(i) Technical Field

The present invention relates to a prosthetic heart valve that has an excellent antithrombotic effect and is durable against long-term use.

(ii) Technical Background

When a heart valve does not function because of disease such as valvular disease, a prosthetic heart valve has been conventionally often used to help smooth blood circulation. Currently available prosthetic heart valves are generally grouped into (1) bioprosthetic valves and (2) non-bioprosthetic valve. The former one is used by securing animal tissue, and there are attempts to use metal, polymer ceramic and so on for the latter one. A bioprosthetic valve may lose its function in relatively short period by lime deposition. On the other hand, non-bioprosthetic valve has a problem of thrombosis. For an ultimate material for a non-bioprosthetic material,

pyrolytic carbon has been developed and currently used very often. In case of this valve, however, the following problems are recognized: (i) noise generation upon opening/closing the valve; (ii) valve damage because of stress applied on the blood vessel or the valve by sudden blood flow change; (iii) generation of thrombus at the valve-attached portion. In order to solve those problems, there has been an attempt of making so-called tricuspid valve having fundamentally improved valve structure from a soft material. In this case, a polymer material having improved antithrombogenicity (especially, polyurethane material) is used as the material, but problems including calcification are not completely solved.

(iii) Disclosure of the Invention

In order to solve the above-described existing various problems, there is provided the present invention. More specifically, the present invention is to use as a heart valve a material comprised of a base material that is essentially made of a polymer material and is coated with diamond or amorphous carbon. A current method of obtaining a diamond or amorphous carbon film is a vapor deposition method, in which hydrocarbon gas is ionized.

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By any of a plasma CVD method, an ion beam vapor-deposition

method, a sputtering method, a crystalline diamond and amorphous carbon can be obtained, but a mixed composition of them can be also obtained. Present inventors found that these films surprisingly have satisfactory properties regarding thrombus and lime deposition, and thereby completed the invention.

The present invention is to compensate some drawbacks of the aforementioned prosthetic heart valve made of pyrolytic carbon by flexibility of a base material. If the valve is a butterfly type like a prosthetic heart valve made of pyrolytic carbon, noise generation or a valve damage accident can be prevented and the antithrombogenecity is not only improved but the whole biocompatibility may be also improved by using a polymer material as an embedding metal fitting. Needless to say, the present invention can achieve the highest effect when the invention is applied as a tricuspid valve. In order to actually implement the invention, a step of vapor-depositing diamond or diamond-like carbon is necessary, but there is no difference in the effects among well-known methods, e.g. an ion beam vapor-deposition method, high-frequency decomposition method, and CVD method. However, a method that does not heat a base material to high temperature is suitably employed, so as not to damage the

base material polymer material itself. Needless to say, a material made of elements having excellent biocompatibility is suitably used as a polymer material for a base material. This is because it is considered that damage in the diamond or diamond carbon from long-term use should not suddenly interfere with use of a valve. Accordingly, polyurethane, silicone, Teflon, and so on may be suitably used.

Working Example 1

A 25mmφx4mm disc was made from polyurethane, and a currently most common B-S valve type heart valve placed in a mount made of polyurethane was made. Furthermore, this polyurethane was coated with an amorphous carbon film for about 2.5 μm by a high-frequency decomposition method of C_2H_6 gas was used as a material of the invention. Embedding these in heart of sheep, a durability test was conducted. A B-S valve made of pyrolytic carbon experienced generation of blood flow disorder due to thrombus. This is because a preventive agent for thrombus was not used, which is conventionally recognized problem. The blood flow disorder seemed to be caused by generation of thrombus from around the valve. On the other hand, a valve that was made solely from polyurethane, blood flow disorder due to calcium deposition occurred in 25 days of use. In case of a material of the invention, there is no trouble even after

120 days of use, and noise generation upon opening/closing a valve is also almost negligible in comparison with a B-S valve made of pyrolytic carbon.